## **REMARKS**

The following issues are outstanding in the pending application:

- Claims 3-8, 10-11 and 14 are rejected under 35 USC § 112;
- Claims 3-8, 10-11 and 14 are rejected under 35 USC § 103; and
- Claims 3-8, 10-11 and 14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting.

### Claim Amendments

Claim 14 has been amended to more clearly define the subject invention. Claim 14 now recites a method of animal weight maintenance that includes the steps of 1) simultaneously providing said animal unlimited quantities of a multi-component foodstuff, the foodstuff comprising two or more compartmentalised food compositions, wherein at least two of the compositions differ from each other by at least 1% on an energy ratio basis in their content of two or more of the following: fat, protein and carbohydrate; and 2) allowing said animal to freely self-select from the compartmentalised food compositions; wherein the driver for the self-selection is based upon a target optimum macronutrient ratio for the animal's metabolic needs. Support for this amendment is found in paragraphs [0039]-[0041] of the specification. No new mater has been added.

## 35 USC § 112

Claims 3-8, 10-11 and 14 are rejected under 35 USC § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Examiner has found the term "diver" to be unclear. Claim 14 has been amended to recite that the "driver for the self-selection is based upon a target optimum macronutrient ratio for the animal's metabolic needs". Thus, this element makes it clear that the "driver" is not based on the animal's desire and behavior. Further, the test data in the application clearly shows that an animal's self-selection is not based upon the "finicky behavior" of cats and dogs. Therefore, Applicant respectfully requests that this rejection be withdrawn.

# 35 USC § 103

Claims 3-8, 10-11 and 14 are rejected under 35 USC § 103(a) as having subject matter unpatentable over U.S. Pub. 2001/00448955 to Foreman et al. taken with U.S. Pat. 6,410,063 to Jewell et al., WO 10/97605 and WO 01/97630 in view of Rice ("The Dog Handbook", pages 48-49); Romsos et al. (JAVMA vol. 182(1), pp 41-43 1983); and further in view of Serpell ("The Domestic Dog", pages 104-106, 1995); and Wills, Josephine ("Adult Maintenance", BSAVA Manual of Companion Animal Nutrition & Feeding, Chap. 3, pages 44-46, 1996), taken with Stein ("Natural Healing for dogs and cats", Publishers: The Crossing Press, Inc. CA 1993, page 54) and Smith ("The Encyclopedia of North American Sporting Dogs", Willow Creek Press, 2002, page 82). Applicant respectfully traverses this rejection.

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Foreman teaches a method for feeding a pet a balanced meal or supplement in which the meal includes a main course 24 having a high protein and fat content, a side dish 26 having a high carbohydrate content and a dog treat 28 preferably in the traditional shape of a bone or biscuit which the dog has been preconditioned to perceive as a reward. The meal is provided in a tray with a removable cover and is divided into separate compartments in which the main course, side dish and treat are placed. The food items placed in the tray for the main course 24, treat 28 and side dish 26 are selected by the assembler of the tray based on the criteria listed in the Foreman specification (Para [0043]) for the main course, side dish and treat. The meal is suppose to provide greater satisfaction and enjoyment for the animal than prior art dog food. The different foodstuffs are intended to be eaten in their entirety and the animal is not meant to self-select from each of these different components.

Jewell discloses a method for inducing a state of ketosis in a canine by means of dietary manipulation. The method comprises feeding to a canine in need of such ketosis, on a regular basis, a diet of a <u>single pet food</u> that includes carbohydrate measured as nitrogen free extract of about 0 to about 20 wt. %, protein of about 25 to about 70 wt. %, and fat of about 20 wt. % to about 70 wt. %. The diet is essentially a high fat, low carbohydrate diet that results in the attainment of a ketonic state (Col. 5, lines 12-13).

WO 01/97605 is directed to a food pack that includes at least two vessels, each containing a pet food product, in which an animal is fed one pet food product for the morning meal and the second pet food product is fed for the afternoon/evening meal (Page 3, lines 24-27; page 4, line 1). One of the pet food products has a higher content of fat than the other pet food product. Thus, the morning meal has a fat content between 20-70% and the afternoon/evening meal has a fat content of between 25-75% in which the afternoon/evening meal should be higher in fat content than the morning meal by at least 5%. WO 01/97630 is

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directed to a dietary regime for companion animals in which <u>one pet food product</u> is fed as the morning meal and a <u>second pet food product</u> is fed as the afternoon/evening meal. The morning meal has a higher protein content that the afternoon/evening meal and the afternoon/evening meal has a higher fat content that the morning meal.

Rice describes free-choice feeding as "leaving a least a one-day supply of premium dry dog food where it is accessible to Daisy at all times." Further, " - - - she should be fed free-choice premium dry puppy food, plus two small daily meals of canned and dry food mixed." The Rice reference, on page 48 in the second paragraph under the heading "Free-Choice Feeding", states "free-choice means leaving at least one day's supply of premium dry dog food where it is accessible to [the dog] at all time". The teaching of Rice allows the dog to "graze" on one type of foodstuff during the day.

Serpell is directed to the evolution, behavior and interactions of dogs. Regarding palatability, Serpell states that dogs prefer meat to vegetable protein and display preferences for one meat over the other. Further, they prefer canned or semi-most food to dry food and cooked to raw meat, and canned meat to the same meat freshly cooked. "Hence, palatability, a concept that is based around the sensory properties of the food, its taste, odour and texture, is an important factor in food selections for the domestic dog." In the Serpell reference at page 104, it states that when a dog is offered a choice between two equally nutritious diets, it will invariably choose one over the other, depending on its sensory response to taste and odor, thus showing a food preference of one over the other.

Romsos describes a study that was done to determine if dogs are able to regulate protein intake independently of energy intake, as it is known that dogs are able to regulate

study would effect protein intake in dogs.

their intake of energy. It was found that by allowing dogs access to 2 diets that differed in protein and by rotating the position of each diet within the cage, the dogs were able to adjust their feeding pattern to maintain a constant protein intake without affecting energy intake. The findings of the experiments determine that <u>palatability alters the protein selection</u> in adult dogs. However, Romsos states that because the concentration of fat in the diet affects the self-selected protein, the fat to carbohydrate ratio was also varied in the 2 lower-protein diets. Romsos only looked at the effect of <u>protein on energy intake and did not vary the amount of carbohydrate and fat</u> (other than to compensate for the varying protein levels). Romsos thus states that it is possible that a ratio of dietary fat to carbohydrate wider than that used in the

The Wills referenced is directed to the general nutrient requirements of dogs and cats in which the composition of a balanced diet and factors affecting food intake are discussed. In the section discussing the feeding regimen for dogs, Wills states that dogs have a good enough appetite to eat all they require in one meal per day and that it is satisfactory to adopt a once-a-day feeding regimen. Regarding the feeding regimen for cats, Wills states that: cats reject diets low in protein because such diets are rather unpalatable. Cats also can detect and may reject diets that are deficient in certain nutrients, such as taurine, niacin and vitamin A. In the Willis reference, an owner is supplying the pet with one pet food product per meal.

The Stein reference states that dogs and cats are generally carnivores and promotes a preservative-free pet food that has about 40% protein, 32% fat and 22% carbohydrate for cats and 22% protein, 17% fat and 53% carbohydrate for dogs. The Smith reference states that dogs and cats are generally carnivores in which dog food should have about 21-26% protein and 8-10% fat.

In KSR, the U.S. Supreme Court reaffirmed the Graham factors in the determination of obviousness under 35 U.S.C. § 103(a). The four factual inquires enunciated therein for determining obviousness are: (1) determining the scope and contents of the prior art; (2) ascertaining the differences between the prior art and the claims in issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) evaluating evidence of secondary

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considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), *KSR Int'l Co.* v. *Teleflex Inc.* 127 S. Ct. 1727, 1734-35, 167 L. Ed. 2d 705, 715 (U.S. 2007).

In this case, neither the level of ordinary skill in the art, nor secondary considerations are at issue. However, in order to assess the scope and content of the prior art properly, a thorough understanding of the invention must be acquired by studying Applicant's claims and the specification. M.P.E.P. § 2141. Thus, the inquiry begins with construction of Applicant's claims, explained below. Next, when ascertaining the differences between the prior art and the claims at issue, both the invention and the prior art references as a whole must be considered, and *all* claim limitations must be considered when determining patentability of Applicant's invention. M.P.E.P. §§ 2141; 2143. When this is properly done in this case, as shown below, it becomes clear that differences exist that preclude obviousness. And finally, the test for obviousness requires identification of a reasonable basis for combining the claimed elements in the claimed fashion. *KSR*, 127 S. Ct. at 1741; M.P.E.P. §2143. As shown below, this requirement is not met in this case, and no *prima facie* case for obviousness is made.

Applying the proper test to this case begins with amended independent claim 14 directed to a method for animal weight maintenance that includes the steps of 1) simultaneously providing the animal unlimited quantities of a multi-component foodstuff, the foodstuff comprising two or more compartmentalised food compositions, wherein at least two of the compositions differ from each other by at least 1% on an energy ratio basis in their content of two or more of the following: fat, protein and carbohydrate; and 2) allowing the animal to freely self-select from the compartmentalised food compositions; wherein the driver for the self-selection is based upon a target optimum macronutrient ratio for the animal's metabolic needs.

The prior art does not teach a method for animal weight maintenance that includes simultaneously providing said animal unlimited quantities of a multi-component foodstuff, allowing the animal to freely self-select from the unlimited quantities of the food compositions in which at least two of the compositions differ from each other by at least 1% on an energy ratio basis in their content of two or more of the following: fat, protein and

carbohydrate, wherein the driver for the self-selection is based upon a target optimum macronutrient ratio for the animal's metabolic needs. Foreman discloses a compartmentalised meal, which contains a main dish, a side dish, and perhaps a treat. The different foodstuffs are intended to be eaten in their entirety and the animal is not meant to self-select from each of these different components in order to obtain its optimum macronutrient ratio for its metabolic needs. An animal self-selecting from the meal described by Foreman to obtain the optimum ratio for its needs at the time, is likely not to consume the whole meal. The animal is therefore likely to not maintain its weight but lose weight since it will not be achieving its required calorie content (by not eating the entire meal). Therefore, Foreman does not in any way teach a method of animal weight maintenance comprising simultaneously providing the animal with unlimited quantities of a multi-component foodstuff. Jewell discloses a method for inducing a state of ketosis in a canine by means of dietary manipulation in which a single pet food product is fed a dog that is essentially a high fat, low carbohydrate diet that results in the attainment of a ketonic state. Both the WO applications teach a pet food diet in which a single pet food product is fed twice a day wherein one product contains 20-70% fat and the other pet food product contains 25-75% fat.. However, when combined with Foreman, none of these three references teach feeding unlimited quantities of the food compositions in which at least two of the compositions differ from each other by at least 1% on an energy ratio basis in their content of two or more of fat, protein and carbohydrate, wherein the driver for the self-selection is based upon a target optimum macronutrient ratio for the animal's metabolic needs.

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Examiner has stated that Rice shows that "free-choice" feeding of dogs is a known method of feeding dogs to prevent obesity or overeating. However, the Rice reference teaches that "free-choice means leaving at least one day's supply of premium dry dog food where it is accessible to [the dog] at all times". This does not teach providing a dog with an unlimited supply of foods having different compositions. The teaching of Rice allows the dog to "graze" on one type of foodstuff. It does not teach allowing an animal to self-select from different types of foodstuff to achieve its target macronutrient ration for it's metabolic needs at that time. The Serpell reference teaches that when a dog is offered a choice between two equally nutritious diets, it will choose one over the other based on the dog's sensory response to taste and odor. In the method of claim 14, the self-selection is based upon a

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target optimum macronutrient ratio for the animal's metabolic needs, not on palatability, nor transient sensory preferences. Applicant respectfully submits that the practice of self-selection does not cure the deficiencies of Foreman and the WO applications as discussed above. The Stein and Smith references do indeed state that dogs and cats are generally carnivores, which means that they generally require higher quantities of protein than fat and carbohydrate in their diet. However, claim 14 recites that the least two of the compositions, in the multi-component food composition differ from each other by at least 1% on an energy ratio basis in their content of two or more of fat, protein and carbohydrate. Combining Foremen with a reference that teaches that dogs and cats require high amounts of quality protein simply because they are carnivores does not make obvious the subject matter of claim

Romsos also does not cure the deficiencies in Foreman and the WO applications. The experiments in Romsos involve giving dogs diets with various protein concentrations. The findings of the experiments determined that <u>palatability alters the protein selection</u> in adult dogs. The method of claim 14 is not concerned with palatability and in fact, the application illustrates the opposite; that palatability is overridden by the macronutrient requirement of the animal and therefore the <u>animal will self-select based on the macronutrient content</u> of the foodstuff. The test data in the specification shows that palatability does not affect the macronutrient ratio selection by the animal. Furthermore, Romsos only looked at the effect of protein on energy intake and did not vary the amount of carbohydrate and fat (other than to compensate for the varying protein levels). Therefore, the animals were not able to vary each macronutrient independently, which means they were not able to meet the optimum macronutrient ratio for their metabolic needs.

Applicant respectfully disagrees with the Examiner that if food containing the carbohydrate, fat and protein contents as shown by the primary references were to be offered in a free-choice feeding method so that the dogs/cats are able to self-select their diet then it can be reasonable expected that they would be driven by their protein intake/requirement, being carnivores. The Examiner further states that because Wills teaches that cats can detect nutritional deficiencies in their diet, animals would be capable of self-regulating their diets based on optimal macronutrient content, which would be expected to be protein because cats

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and dogs are carnivorous. In Wills, the low protein diets are rejected by cats because they are unpalatable, not because they do not have an optimal macronutrient content.

In order to make a proper prima facie case for obviousness, all claim limitations must be accounted for. M.P.E.P. § 2143.03. This rejection fails to consider all elements of the claims and their meaning as the cited references do not include all elements of independent claim 14. This is because this combination of references does not teach a method of animal weight maintenance that includes the steps of 1) simultaneously providing the animal unlimited quantities of a multi-component foodstuff, the foodstuff comprising two or more compartmentalised food compositions, wherein at least two of the compositions differ from each other by at least 1% on an energy ratio basis in their content of two or more of the following: fat, protein and carbohydrate; and 2) allowing the animal to freely self-select from the compartmentalised food compositions; wherein the driver for the self-selection is based upon a target optimum macronutrient ratio for the animal's metabolic needs. As discussed above, Foreman does not in any way teach a method of animal weight maintenance comprising providing the animal with unlimited quantities of a multi-component foodstuff. Jewell and the two WO applications when combined with Foreman, do not teach feeding unlimited quantities of the food compositions in which at least two of the compositions differ from each other by at least 1% on an energy ratio basis in their content of two or more of the following: fat, protein and carbohydrate, wherein the driver for the self-selection is based upon a target optimum macronutrient ratio for the animal's metabolic needs. The free-choice feeding described in the various references does not teach providing an unlimited amount of foodstuff. Free-choice feeding is described as provisioning out a one-day supply of a single pet food that would be allowed to the animal in one meal, allowing the animal to eat the amount that it likes and return later to finish the food. Free-choice feeding does not provide different foodstuffs to the animal at the same time, allowing it to self-select between the foodstuffs to achieve its optimum macronutrient ratio, and therefore meet its metabolic needs. Nor do the references that rely on palatability add any additional relevant teaching to the list of cited references that would make obvious the method of claim 14. Thus, the claims are erroneously rejected over the cited references and Applicant respectfully requests the rejection be removed. Applicant respectfully asserts that modifying the teaching of Foreman et al., with Jewell et al., the two WO applications, Rice, Romsos et al., Serpell, Wills, Stein 60213564.1

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and Smith references will not provide the method of independent claim 14. Therefore, Applicant respectfully submits that independent amended claim 14is not obvious.

If an independent claim is non-obvious under 35 U.S.C. 103, than any claim depending therefrom is by definition non-obvious. Applicant respectfully submits that claims 3-8, 10 and 11 depend at least in part from amended independent claim 14. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection of claims 3-8, 10, 11, and 14 under 35 U.S.C. 103(a) as having subject matter unpatentable over U.S. Pub. 2001/00448955 to Foreman et al. taken with U.S. Pat. 6,410,063 to Jewell et al., WO 10/97605 and WO 01/97630 in view of Rice ("The Dog Handbook", pages 48-49); Romsos et al. (JAVMA vol. 182(1), pp 41-43 1983); and further in view of Serpell ("The Domestic Dog", pages 104-106, 1995); and Wills, Josephine ("Adult Maintenance", BSAVA Manual of Companion Animal Nutrition & Feeding, Chap. 3, pages 44-46, 1996), taken with Stein ("Natural Healing for dogs and cats", Publishers: The Crossing Press, Inc. CA 1993, page 54) and Smith ("The Encyclopedia of North American Sporting Dogs", Willow Creek Press, 2002, page 82).

### **Double Patenting**

The claims have been rejected for obviousness-type double patenting in view of claims 1-15 of 10/742360. No patent has issued yet from U.S. Patent Application No. 10/742360, thus a rejection on the basis of double patenting is premature and Applicants treat it as a *provisional* rejection on the stated basis. Provisional double patenting rejections of this type do not require Applicants' to act at this time. The Court of Claims and Patent Appeals (now the Court of Appeals for the Federal Circuit) has stated, "Once the provisional rejection has been made, there is nothing the examiner and the applicant must do until the other application issues." *In re Mott*, 190 U.S.P.Q. 536, 541 (C.C.P.A. 1976). In fact, the amendments made herein above render the current double patenting rejection moot. M.P.E.P. section 804 allows for the prosecution to continue while a provisional double-patenting rejection is pending and even instructs the Office to continue to make such a provisional rejection until one of the applications issues as a patent. Thus, the rejection is noted, and Applicants' will address the rejection appropriately once one of the asserted conflicting claim sets has been deemed allowable.

# **CONCLUSION**

Applicants believe the above addresses all outstanding issues and the Application is now in condition for allowance.

The fee for a three month extension of time is being submitted with this response. The fee for the RCE is also being submitted with this response. If additional fees are due, please charge our Deposit Account No. 06-2375, under Order No. HO-P03188US0, from which the undersigned is authorized to draw.

Dated: November 24, 2009 Respectfully submitted,

Electronic signature: /Jan K. Simpson/

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